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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/507,360	01/28/2005	Steven Streatfield Gill	3174.00010	5703
7590	03/27/2006		EXAMINER	
Kenneth I Kohn Kohn & Associates Suite 410 30500 Northwestern Highway Farmington Hills, MI 48334			POUS, NATALIE R	
			ART UNIT	PAPER NUMBER
			3731	
DATE MAILED: 03/27/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/507,360	<b>Applicant(s)</b> GILL, STEVEN STREATFIELD	
	<b>Examiner</b> Natalie Pous	<b>Art Unit</b> 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 28 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 7-9 is/are rejected.
- 7) ☒ Claim(s) 6, 10-15 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION*****Information Disclosure Statement***

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

***Drawings***

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: 16, 17, 18, 19. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Claim Objections***

Claim 7 objected to because of the following informalities: claim 7 depends off "any one of the preceding claims." For the purpose of examination, this will be interpreted as dependent off of claim 1 since all preceding claims depend from claim 1, and therefore claim 1 is included in each preceding claim. However, based on this interpretation, claims 13-15 lack antecedent basis since the second clamp is not introduced until claim 2. It is therefore unclear as to which claim or claims the method (claims 7-15) depends from. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Line 3 refers to "characterized by a first clamp." It is unclear whether the clamp limitation is describing the guide element, or the clamp is separate of the guide element, or if the clamp is part of the guide element structure. It is also possible that the clamp is characterizing the stereoguide. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3 and 4 rejected under 35 U.S.C. 102(b) as being anticipated by Warner et al. (US 5643286).

Regarding Claim 1, Warner teaches a stereoguide comprising first (16) and second (12) guide elements through which instruments are passed along an axis of insertion towards a target; characterized by a first clamp (38) having a clamping position on the axis between the guide elements and the target, or on the opposite side (16, 12) of the guide elements for clamping instruments passing through the guide elements (fig. 1).

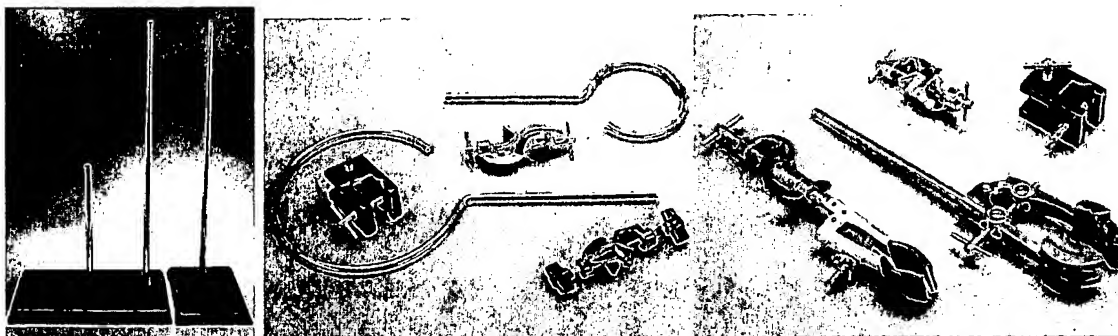
Regarding claim 3, Warner teaches a stereoguide according to claim 1, wherein the or each clamp (38) is moveable away from its clamping position (it is noted that clamp (38) is a screw that untwists from portion (32) to unclamp).

Regarding Claim 4, Warner teaches a stereoguide according to claim 3, wherein the or each clamp is swivelable away from its clamping position (it is noted that screw head (38) "swivels" when twisted).

Claims 1-5 are rejected under 35 U.S.C. 102(a) as being anticipated by Indigo Instruments (<http://www.indigo.com/>). Indigo asserts that the combination of posts, guide members and clamps may be used for any experimental setup figure d) below,

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simply illustrates an example of an experimental setup. Therefore, Indego teaches a device capable of use as a comprising first and second guide elements through which instruments are passed along an axis of insertion towards a target; characterized by a first clamp having a clamping position on the axis between the guide elements and the target, or on the opposite side of the guide elements for clamping instruments passing through the guide elements. Further comprising a second clamp having a clamping position on the axis of insertion and on the opposite side of the guide elements to the first clamp for clamping instruments passing through the guide elements wherein the or each clamp is moveable away from its clamping position. wherein the or each clamp is swivelable away from its clamping position, and wherein the second clamp is disposed between the guide elements and the target.

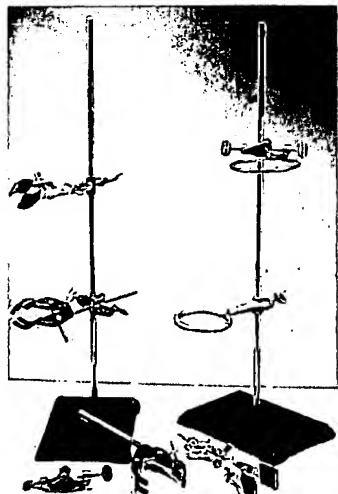


a) posts  
<http://www.indigo.com/science-supplies/gph-science-supply/cast-iron-labstands.html>

b) guide members  
[http://www.indigo.com/science-supply/bossheads-rings.html](http://www.indigo.com/science-supplies/gph-science-supply/bossheads-rings.html)

c) clamps  
<http://www.indigo.com/science-supplies/gph-science-supply/bossheads-clamps.html>

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d)  
<http://www.indigo.com/science-supplies/gph-science-supply/lab-support-stand.html>

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 7, 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Warner in view of Durand (US 4504269). Warner teaches a stereoguide comprising all limitations of preceding dependent claim 1 as previously described, but fails to disclose the method of: inserting a wire into a support tube; insertion towards the target via the guide elements of the stereoguide; removing the support tube from the wire, leaving the wire in situ; inserting a guide tube around the wire towards the target; securing the guide tube in position; removing the wire; and inserting the instrument to the target via the guide tube. Warner does teach the method wherein obturator (57) and cannula (50) are inserted at the same time, and obturator (57) is then removed leaving cannula (50) in place. Examiner asserts that the method described in the application is a well known tube introduction method known as the "Seldinger Technique" described in the "Acta Radiologica" journal in 1953 and utilized in Durand. According to this well-known method for introducing a tubular member into the body and as illustrated by Durand in figs. 9A-9J), a needle that inserted into the body, and a wire is inserted through the needle; the needle is then removed. The tube is then threaded into the body by being guided by the wire over which it is moving. The wire is then removed from the tube. This method is utilized in order to provide a less traumatic entry technique. It would have been obvious to one of ordinary skill in the art at the time the invention was made to perform the "Seldinger Technique" of insertion for the instrument holding cannula (50) with the device of Warner as taught by Durand in order to provide a less traumatic entry technique for the cannula.



The combination of Warner and Durand further teaches wherein the insertion of the wire into the support tube results in the wire projecting from the end of the support tube (it is noted that in order to remove the insertion wire as required by Durand, the wire must be longer than the support tube).

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Warner in view of Durand and further as a matter of design choice.

The combination of Warner and Durand teaches all of the limitations of preceding dependent claims 1, 7 and 8 as previously described, but fails to disclose wherein the wire projects from the support tube towards the target by about 25mm. Since the applicant has not disclosed that the wire projecting about 25mm from the support tube, solves any particular problem or provides any advantage over a system wherein the length of wire projecting past the support tube is not disclosed, it would have been an obvious matter of design choice to provide the wire about 25mm past the support tube, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum range involves only routine skill in the art. In re Aller, 105 USPQ 184.

#### ***Allowable Subject Matter***

Claims 6, and 10-15 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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### **Conclusion**

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.


Sven-Ivar Seldinger: Catheter replacement of the needle in percutaneous arteriography (a new technique). Acta Radiologica, Stockholm, 1953, 39: 368-376.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie Pous whose telephone number is (571) 272-6140. The examiner can normally be reached on Monday-Friday 8:00am-5:30pm, off every 2nd Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NRP  
3/14/06

  
(JACKIE) TAN-UYEN HO  
PRIMARY EXAMINER

3/17/06